



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS-0990-0263-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990-0263, which expires on March 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990-0263 for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form – Extension OMB No. 0990-0263, Assistant Secretary for Health, Office for Human Research Protections.
OMB No.: 0990-0263

Abstract: The Office for Human Research Protections is requesting a three year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)].

Need and Proposed Use of the Information: The information collected through the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form is the minimum necessary to satisfy the assurance and certification requirements of Section 491 (a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or –supported research involving human subjects. Institutional use of the form is also relied upon by

other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

Total Estimated Annualized Burden - Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	12,000	2	30/60	12,000
Total				12,000

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor

Information Collection Clearance Officer

